

REMARKS

Claims 39-57 and 59-65 are pending. Claims 39-44 are withdrawn from consideration as being drawn to a nonelected invention. Claim 51 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 45, 47, 52-53, 55-56 and 60 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sugano et al., U.S. Patent No. 4,416,606 (“Sugano”) or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sugano in view of Martin (2001). Claims 46, 54 and 59 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sugano or, in the alternative, Sugano in view of Martin. Claims 61-65 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sugano or, in the alternative, Sugano in view of Martin, and further in view of Gamlen et al., *Drug Development and Industrial Pharmacy* 12:1701-1715, 1986 (“Gamlen”). Claims 45-46, 48-54, 57, 59-61 and 63-64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gamlen in view of Sugano or, in the alternative, Gamlen in view of Sugano and Martin.

Claim Amendments

Claims 48 and 53-54 have been amended to delete the word “about” at each occurrence.

Claims 59 and 65 have been cancelled.

Claim 45 has been amended to recite “said second transport zone (8) having an aperture (9) positioned collinearly to said continuously operating transport system.” This amendment finds support, for example, in the abstract of U.S. provisional application No. 60/429,214 from which this application claims benefit.

Claim 51 has been amended by deleting the objected wording “belonging to Class II or Class IV of the Biopharmaceutical Classification System.”

Claim 52 has been amended by deleting the term “chemicals” from the Markush group.

No new matter has been added by these amendments.

Applicants note that the present amendments have been made to advance prosecution. Applicants reserve the right to pursue any cancelled subject matter in this or a continuing application.

Rejection under 35 U.S.C. § 112, Second Paragraph

Amended claim 51 no longer includes the objected phrase “belonging to Class II or Class IV of the Biopharmaceutical Classification System.” This ground for rejection should therefore be withdrawn.

Rejection under 35 U.S.C. § 102(b)/ 103(a) - Claims 45, 47, 52-53, 55-56, and 60

Claims 45, 47, 52-53, 55-56, and 60 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Sugano or, in the alternative, under 35 U.S.C. § 103 (a) as being obvious over Sugano in view of the newly cited reference Martin.

In response to the Applicant's argument filed May 15, 2009 (page 14) that the Examiner does not direct applicant to where Sugano teaches directly discharging granules without submission to any pressure gradient, the Examiner now states that this results from figure 5 (reference number 8) and that the zero pressure gradient is inherent to the machine's open design (2:24), i.e. assumingly the sentence "*the breaking zone is of an open structure*" at column 2 line 24 of Sugano.

The breaking zone referred to in the latter sentence is the breaking zone III extensively disclosed at column 3 lines 46-49 of Sugano, not the downstream section of the kneading zone II of Sugano. On this basis alone, Sugano does not anticipate claim 45.

Furthermore, the Examiner's analysis of Sugano to assimilate the breaking zone III to a portion of the kneading zone II in order to assert that step (e) is anticipated by, or inherent taught by, the quoted portions of Sugano is improper. As the Federal Circuit has held in *Net MoneyIn Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008):

"Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged

as in the claim.”” (citation omitted.) Indeed, to reconstruct the actual teaching of the prior art differently from what the prior art meant to the skilled person at the time when the invention was made is legally incorrect. It remains applicant’s position that a zero pressure gradient is not inherent to Sugano’s machine.

Applicants disagree with the Office’s interpretation of Sugano for another reason. Sugano’s material passes through a restricted discharge port (8) which is at a 90 degree angle to the kneading zone II₂. This construction reasonably effects a pressure gradient. Absent evidence to the contrary, it appears that Sugano’s breaking zone III therefore submits material received from zone II₂ to a pressure gradient due to the existence of the turned restricted discharge port (8). Accordingly, Sugano’s method fails to meet the requirements of applicants’ amended claim 45, especially the features of steps (d) and (e).

For the foregoing reasons, Sugano fails to anticipate claim 45 and this rejection should be withdrawn. The same conclusion holds true for all claims which directly or indirectly depend upon claim 45, in particular dependent claims 47, 52-53, 55-56 and 60.

In particular the amount by weight of liquid taught by Sugano, as indicated by the Examiner at page 4 lines 1-2 of the Office Action, is well below the weight amount range of claim 53.

Martin teaches, with reference to figure 7 entitled “Pressure profile in a twin screw extruder” that “*the pressure gradient in a twin screw extruder is controlled and kept at zero for much of the process*” (paragraph above figure 7). However Martin fails to

disclose a wet granulation process, whereby the resulting product is in the form of granules, and fails to teach the initial feeding of a powder material. Rather, it is clear from the introduction of Martin (page 1) that this reference addresses extruded products ranging from pellets and fibers to tubes, films and sheets of polymer resins. It has been made very clear in the background section of this application how wet granulation processes distinguish from extrusion processes, in particular see page 2 line 18 to page 3 line 18 as opposed to page 3 line 19 to page 4 line 13. Briefly, extrusion involves a single phase homogeneous material, usually a molten material (metal, alloy, plastics), operated at high temperatures (usually not less than 200°C). Wet granulation involves a two-phase heterogeneous system that includes granulating liquid and solid particles, operated at moderate or low temperatures.

Nothing in Martin teaches or suggests the initial feeding of a granulating liquid to the same first transport zone as the powder material as required in step (b) of claim 45. The person skilled in the art of polymer compounds knows that granulating liquids are normally not introduced in the early stage of continuous compounding processes using twin-screw extruders. Rather, Martin discloses (page 9) the downstream feeding of liquids that can be accomplished through injection ports for liquids, but does not suggest that such liquids may perform a wet granulating function. Therefore the skilled person would not look at the extrusion teaching of Martin when attempting to improve or modify the granulation process of Sugano for any reason. The skilled person would not be

motivated to consider Martin, since Martin has too many features different from the teaching of Sugano: no granulating liquid, no powder material, and no granule production. This distinction is made clear in claim 45 which does not refer to an extruder or an extruding step.

Accordingly claim 45 is not obvious over Sugano in view of Martin, and this rejection should be withdrawn. The same conclusion holds true for all claims which directly or indirectly depend upon claim 45, in particular dependent claims 47, 52-53, 55-56 and 60. In particular Martin does not teach or suggest the type of powder material listed in claim 52. Martin does not suggest using a granulating liquid in the weight amount range specified by claim 53. Martin does not suggest granule drying (claim 55) or granule milling (claim 56). Sugano at best teaches sodium percarbonate, a chemical which is no longer recited in amended claim 52.

Rejection under 35 U.S.C. § 103(a) - Claims 46, 54, and 59

Claims 46, 54, and 59 are rejected under 35 U.S.C. § 103 (a) as being obvious over Sugano in view of the newly cited reference Martin. Claim 59 is now cancelled.

Each of claims 46 and 54 depends from claim 45, and incorporates the limitations of claim 45. “[O]bviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Even assuming in arguendo that the additional

agglomeration zones (claim 46) and operating temperature (claim 56) would have been obvious to an ordinary artisan, the artisan would not, for reasons set forth hereinabove, have been prompted to modify Sugano's teachings to arrive at a method that includes steps (d) and (e) as now recited in amended claim 45. Thus, each of these rejections should also be withdrawn.

Rejection under 35 U.S.C. § 103(a) - Claims 45-46, 48-54, 57, 59, and 61-65

Claims 61-65 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sugano or, in the alternative, Sugano in view of Martin, and further in view of Gamlen et al., *Drug Development and Industrial Pharmacy* 12:1701-1715, 1986 ("Gamlen"). Claims 45-46, 48-54, 57, 59-61 and 63-64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gamlen in view of Sugano or, in the alternative, Gamlen in view of Sugano and Martin.

The subject matter of amended claim 45 corresponds to the subject matter of claim 65, which has been cancelled. All pending claims 46-57 and 60-64 directly or indirectly depend upon claim 45. Claim 45, as amended, is plainly not obvious over Sugano in view of Martin, and further in view of Gamlen.

The Examiner asserts that:

- Sugano's method is a remedy to the deficiencies of the extrusion method of Gamlen (paragraph bridging pages 6 and 7 of the Office Action), and

- Gamlen teaches (figure 1) a discharge aperture collinear to the machine, which the skilled artisan would have obviously substituted for the non-collinear aperture of Sugano (second paragraph of page 6 of the Office Action).

Applicants submit that these two statements are clearly incompatible. The skilled person is taught away from Gamlen by the technical deficiencies associated with a pharmaceutical extrusion process, and would therefore have no motivation to import any specific feature of Gamlen, such as the collinear aperture, into the wet granulation process of Sugano. Because Martin equally refers to an extrusion process like Gamlen, and because Martin was merely cited to support the teaching of a zero pressure gradient, consideration of Martin together with Gamlen and Sugano does not change the non-obviousness situation. The Sugano reference in view of Gamlen simply would not lead one of ordinary skill in the art to the method of amended claim 45.

Because the Office has failed to present a *prima facie* case of obviousness against current claim 65, the same situation applies to amended claim 45 and claims 46-57 and 60-64 directly or indirectly depending upon claim 45. The rejections of these claims should likewise be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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